

Food and Drug Administration Rockville MD 20857

FILE COPY

October 16, 2000

Gordon R. Johnston Lachman Consultant Services, Inc. 1600 Stewart Avenue Westbury, NY 11590

Dear Mr. Johnston:

Your petition requesting the Food and Drug Administration to make a determination that Abbreviated New Drug Application (ANDA) may be submitted for Ursodiol Oral Suspension, 20 mg/mL in a ready-to-use form for oral administration, was received by this office on 10/16/00. It was assigned docket number 00P-1568/CP 1 and it was filed on 10/16/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega

Dockets Management Branch

OOP-1568

ACRI